

CIRCUIT COURT
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CITY OF ROANOKE

VIRGINIA:

IN THE CIRCUIT COURT FOR THE CITY OF ROANOKE

JAMES WIRT SMITH, JR.,

Plaintiff,

v.

INSIGHT HEALTH CORP.,
CT Corporation System, Its Registered Agent
4701 Cox Road, Suite 301
Glen Allen, Virginia 23060
(Henrico County)

JOHN M. MATHIS, M.D.,
2923 Franklin Rd., S.W.
Roanoke, Virginia 24014
(Roanoke City)

ROBERT F. O'BRIEN, M.D.,
2923 Franklin Rd., S.W.
Roanoke, Virginia 24014
(Roanoke City)

AND

IMAGE GUIDED PAIN MANAGEMENT,
P.C.,
Heman A. Marshall, Esq., Its Registered Agent
Woods Rogers, PLC
Wells Fargo Tower, 14th Floor
Roanoke, Virginia 24011
(Roanoke City)

Defendants.

Case No: CL 12-2572

COMPLAINT

COMES NOW James Wirt Smith, Jr., by counsel, and files this Complaint against the
Defendants and states as follows:

PARTIES

1. Mr. Smith is a citizen of the state of West Virginia.
2. Insight Imaging-Roanoke is located at 2923 Franklin Road, S.W. Roanoke, Virginia 24014.
3. Insight Imaging-Roanoke is a registered fictitious name of Image Guided Pain Management, P.C. ("Image Guided").
4. Insight Health Corp. ("Insight Health") transacts business in the Commonwealth of Virginia under the fictitious name of Insight Imaging-Roanoke.
5. Insight Health has not registered the fictitious name of Insight Imaging-Roanoke in violation of Virginia Code §§ 59.1-69 and 59.1-70.
6. At all times and places pertinent to this action, Insight Health transacted business in the Commonwealth of Virginia under the fictitious name of Insight Imaging-Roanoke.
7. At all times and places pertinent to this action, Insight Health owned, operated and controlled Insight Imaging-Roanoke.
8. Unless otherwise specified in this Complaint, references to Insight Imaging-Roanoke include Image Guided and Insight Health.
9. At all times and places pertinent to this action, Insight Health made the actual decisions and arrangements relating to the selection, procurement, and preparation of drugs administered at Insight Imaging-Roanoke, including the epidural steroid drug which is at issue in this case.
10. Insight Health is incorporated in the State of Delaware.
11. Insight Health's principal place of business is in the State of California.

12. At all times and places pertinent to this action, Insight Health advertised to the public that it was a national provider of diagnostic imaging services.

13. At all times and places pertinent to this action, Insight Health advertised to the public that it was committed to providing the best imaging experience possible, and it called this "Patients First care".

14. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was to "do the right thing".

15. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was integrity.

16. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values was ethics.

17. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values of doing the right thing, integrity, and ethics took priority over profits.

18. At all times and places pertinent to this action, Insight Health advertised to the public that one of its core values of doing the right thing, integrity, and ethics took priority over expediency.

19. At all times and places pertinent to this action, Insight Health advertised to the public that it offered the highest quality of care through a network of outpatient imaging centers and mobile facilities.

20. At all times and places pertinent to this action, Insight Health advertised to the public that one of its centers was Insight Imaging-Roanoke, located at 2923 Franklin Road, S.W. Roanoke, Virginia 24014.

21. At all times and places pertinent to this action, Insight Health advertised to the public that one of the modalities that it provided at Insight Imaging-Roanoke was pain management image-guided therapeutics.

22. Insight Health procured, received, and provided to Mr. Smith the epidural steroid injection which is at issue in this case.

23. Dr. John M. Mathis ("Dr. Mathis") is a citizen of the Commonwealth of Virginia.

24. At all times and places pertinent to this action, Insight Imaging-Roanoke allegedly designated Dr. Mathis as its medical director.

25. At all times and places pertinent to this action, Insight Imaging-Roanoke allegedly held Dr. Mathis out to the public as its medical director.

26. On information and belief, Dr. Mathis would allege that Insight Imaging-Roanoke designated him as its medical director without his permission or consent.

27. On information and belief, Dr. Mathis would allege that Insight Imaging-Roanoke held him out to the public as its medical director without his permission or consent.

28. On information and belief, Dr. Mathis would allege that Insight Imaging-Roanoke never asked him to be its medical director.

29. On information and belief, Dr. Mathis would allege that he never gave his permission or consent to be Insight Imaging-Roanoke's medical director.

30. On information and belief, Dr. Mathis would allege that he was never compensated to be Insight Imaging-Roanoke's medical director.

31. On information and belief, Dr. Mathis would allege that he never acted as Insight Imaging-Roanoke's medical director.

32. If Dr. Mathis agreed to be or acted as the medical director of Insight Imaging-Roanoke during the times and places pertinent to this action, then he was ultimately responsible for Insight Imaging-Roanoke's choices regarding the procurement of drugs, such as Mr. Smith's epidural steroid drug which is at issue in this case.

33. If Dr. Mathis did not agree to be or act as the medical director of Insight Imaging-Roanoke during the times and places pertinent to this action, then Insight Imaging-Roanoke falsely designated and held out Dr. Mathis to the public as its medical director, and Insight Health delegated to non-medical staff the important patient care function of choosing safe and effective drugs for its patients.

34. At all times and places pertinent to this action, Dr. Mathis was an employee and/or agent of Insight Imaging-Roanoke acting in the course and scope of his employment or agency.

35. At all times and places pertinent to this action, Insight Imaging-Roanoke acted through its employees and agents including, but not limited to, Dr. Mathis.

36. At all times and places pertinent to this action, Insight Imaging-Roanoke was vicariously liable for Dr. Mathis' actions and omissions.

37. Dr. Robert F. O'Brien ("Dr. O'Brien") is a citizen of the Commonwealth of Virginia.

38. Dr. O'Brien performed Mr. Smith's epidural steroid injection at Insight Imaging-Roanoke.

39. At all times and places pertinent to this action, Dr. O'Brien was an employee and/or agent of Insight Imaging-Roanoke acting in the course and scope of his employment or agency.

40. At all times and places pertinent to this action, Insight Imaging-Roanoke acted through its employees and agents including, but not limited to, Dr. O'Brien.

41. At the times and places pertinent to this action, Insight Imaging-Roanoke was vicariously liable for Dr. O'Brien's actions and omissions.

42. At all times and places pertinent to this action, Insight Imaging-Roanoke also did business through other employees and agents located in Roanoke and other places in the United States including, but not limited to, Paul Hellkamp, secretaries, nurses, technicians, staff, and personnel.

43. At the times and places pertinent to this action, Insight Imaging-Roanoke was vicariously liable for the actions and omissions of its other employees and agents located in Roanoke and other places in the United States including, but not limited to, Paul Hellkamp, secretaries, nurses, technicians, staff, and personnel.

44. Image Guided is incorporated in the Commonwealth of Virginia.

45. Image Guided's principal place of business is in the City of Roanoke, Virginia.

JURISDICTION AND VENUE

46. Subject matter jurisdiction is proper pursuant to Virginia Code § 17.1-513.

47. Personal jurisdiction over Insight Health is proper pursuant to at least Virginia Code §§ 8.01-328.1(A)(1), (2), (3), (4) & (6).

48. Personal jurisdiction over Image Guided, Dr. Mathis, and Dr. O'Brien is proper pursuant to at least Virginia Code §§ 8.01-328.1(A)(1), (2), (3) & (6).

49. Venue is proper pursuant to Virginia Code §§ 8.01-262(1) & (2).

FACTS

50. At all times and places pertinent to this action, Insight Imaging-Roanoke and its employees and agents had a healthcare provider-patient relationship with Mr. Smith.

51. Insight Imaging-Roanoke and its employees and agents owed Mr. Smith numerous duties including, without limitation, the following: to act as reasonable and prudent healthcare providers; to provide the best imaging experience possible; to act ethically; to act with integrity; to do the right thing; to place patient care first; to place ethics, integrity, doing the right thing, and patient care above profits; and to ensure that the drugs that they gave to patients were safe and effective.

52. At all times and places pertinent to this action, Mr. Smith relied upon the advice and treatment provided by Insight Imaging-Roanoke and its employees and agents, which had specialized training and superior knowledge regarding treatment, use of drugs, and the source of drugs.

53. Insight Imaging-Roanoke and its employees and agents intended to and in fact did use methylprednisolone acetate in epidural steroid injections, including the injection provided to Mr. Smith which is at issue in this case.

54. The use of methylprednisolone acetate in epidural steroid injections by Insight Imaging-Roanoke and its employees and agents has never been approved by the Food and Drug Administration ("FDA").

55. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the use of methylprednisolone acetate in epidural steroid injections has never been approved by the FDA.

56. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that use of methylprednisolone acetate in epidural steroid injections is an off-label use.

57. Insight Imaging-Roanoke and its employees and agents knew, or should have known, the importance of purchasing safe and effective drugs for their patients and this importance was greatly heightened by the fact that the use of methylprednisolone acetate in epidural steroid injections has never been approved by the FDA.

58. Insight Imaging-Roanoke and its employees and agents knew, or should have known, the danger to which their patients would be exposed if they purchased unsafe and/or ineffective drugs for its patients.

59. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the best way of ensuring safe and effective drugs for their patients was to purchase such drugs from an FDA-regulated manufacturer or an accredited pharmacy that complied with all federal and state laws.

60. Insight Imaging-Roanoke and its employees and agents assumed the responsibility for purchasing safe and effective drugs for its patients, including Mr. Smith.

61. Insight Imaging-Roanoke and its employees and agents assumed the responsibility for verifying that the pharmacy from which they purchased drugs was safe, reliable, accredited and in compliance with all federal and state laws.

62. New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC") was a compounding pharmacy located in Framingham, Massachusetts.

63. Compounding pharmacies are generally small operations that engage in mixing (or "compounding") drug products for specific patients, pursuant to a valid prescription.

64. Because they typically compound drug products in forms that are not commercially available, compounding pharmacies are not regulated by the FDA.

65. Rather, compounding pharmacies are generally regulated under state law applicable to pharmacies and pharmacists.

66. Although NECC operated in Massachusetts, it was also required to comply with Virginia law in order to fill prescriptions in Virginia.

67. NECC was required to be licensed and registered with the Virginia Board of Pharmacy.

68. Methylprednisolone acetate is a knock-off of the brand name drug, Depo-Medrol, which is manufactured by the FDA-regulated company, Pharmacia & Upjohn Company, a Division of Pfizer, Inc. ("Pfizer").

69. Other FDA-regulated drug manufacturers produce sterile generic versions of methylprednisolone acetate (with and without preservatives) in facilities that are also regulated, controlled, and inspected by the FDA.

70. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that sterile methylprednisolone acetate (with and without preservatives) may be purchased in generic form from FDA-regulated drug manufacturers in the United States.

71. Rather than producing small quantities of this knock-off Depo-Medrol, NECC engaged in the very risky process of producing and marketing vast batches of this drug, thousands at a time.

72. NECC did so through a process of taking non-sterile ingredients and placing them into an aqueous mixture that then had to be rendered sterile.

73. Even without the large batches, NECC's process made the methylprednisolone acetate a high risk compound.

74. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC engaged in the process of producing and marketing vast batches of this drug.

75. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC's process made the methylprednisolone acetate a high risk compound.

76. NECC acted as a wholesale distributor by selling large quantities of methylprednisolone acetate.

77. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC acted as a wholesale distributor by selling large quantities of methylprednisolone acetate.

78. Under Virginia law, compounding pharmacists must ensure compliance with USP-NF standards (United States Pharmacopeial National Formulary). Virginia Code §54.1-3410.2(E).

79. NECC failed to comply with USP-NF standards.

80. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was not compliant with USP-NF standards.

81. Moreover, pharmacists and pharmacies may not engage in "the regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products." Virginia Code §54.1-3410.2(H)(2).

82. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was producing enormous batches of commercially available methylprednisolone acetate, which NECC then sold in bulk.

83. Within just two months during the general time frame pertinent to this action, Insight Imaging-Roanoke alone purchased and injected over 600 doses of methylprednisolone acetate from NECC.

84. Such large-scale production of methylprednisolone acetate, a commercially available drug, is illegal under Virginia Code § 54.1-3410.2(H)(2).

85. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC's large-scale production of methylprednisolone acetate and subsequent sale without individual prescriptions violated Virginia law.

86. NECC is not accredited by the Pharmacy Compounding Accreditation Board ("PCAB") or any other similar organizations, such as The Joint Commission, that offer independent assurance as to the quality and competence of compounding pharmacies that meet certain requirements.

87. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was not an accredited compounding pharmacy.

88. There are accredited compounding pharmacies in the Commonwealth of Virginia and the United States, but Insight Imaging-Roanoke and its employees and agents chose not to purchase drugs from them, electing instead to buy methylprednisolone acetate from an unaccredited, wholesale distributor pharmacy facility in Massachusetts—a state known to have less stringent enforcement standards for compounding pharmacies than the Commonwealth of Virginia.

89. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that there are accredited compounding pharmacies in the Commonwealth of Virginia and the United States.

90. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that Massachusetts, the state in which NECC was located, had less stringent enforcement standards for compounding pharmacies than the Commonwealth of Virginia.

91. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the methylprednisolone acetate that it sought to purchase was to be used in epidural steroid injections allowing direct contact with patients' central nervous systems, including Mr. Smith's central nervous system.

92. NECC produced methylprednisolone acetate without preservatives.

93. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC produced methylprednisolone acetate without preservatives.

94. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that preservative free methylprednisolone acetate heightens the danger of the drug if it is not produced to the highest standards including a highly sterile environment.

95. Sterilization techniques, quality control measures, highly sterile environments and sterility testing are crucial to properly producing methylprednisolone acetate without preservatives.

96. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that sterilization techniques, quality control measures, highly sterile environments, and sterility testing were crucial to the methylprednisolone acetate that they were going to inject in its patients' spinal canals.

97. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was an unaccredited compounding pharmacy producing a high-risk compound, starting with non-sterile components.

98. NECC's drug production operations took place in an aged building surrounded by a waste recycling center owned by one of the co-owners of NECC, Gregory Conigliaro.

99. NECC's drug production facility received many varieties of garbage and waste that were sorted, stored, and manipulated just outside the back door of the NECC facility.

100. These waste products include used mattresses, recycled on-site from sources such as hospitals, prisons, hotels, and dormitories.

101. A photograph of NECC's facility is attached as **Exhibit A**.

102. It is difficult to distinguish where NECC ends and the waste recycling center begins, if there is such a distinction in fact; but the waste facility lists its address as 701 Waverly Street, Framingham, Massachusetts while NECC lists its address as 697 Waverly Street.

103. The marketing company for NECC, however, lists its address as the same as the waste facility.

104. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC's drugs and production processes were unsanitary, unsterile, and lacked adequate quality control measures, and that NECC operated in a facility surrounded by a garbage and waste center.

105. Other image guided pain management clinics in the Roanoke area recognized NECC as a dangerous source of methylprednisolone acetate.

106. These other clinics chose to pay more to obtain methylprednisolone acetate from reliable sources, specifically rejecting the lower prices offered by NECC.

107. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was a dangerous source of methylprednisolone acetate.

108. On information and belief, NECC charged Insight Imaging-Roanoke less for methylprednisolone acetate than did Pfizer, other FDA approved manufacturers of the generic, and other accredited or reliable compounding pharmacies.

109. At all times and places pertinent to this action, Insight Imaging-Roanoke was one of only two pain management clinics in the Commonwealth of Virginia that chose to purchase methylprednisolone acetate from NECC.

110. Under Virginia Code §54.1-3435.01(A), non-resident pharmacies that engage in wholesale distribution of prescription drugs into the Commonwealth of Virginia must register with and be licensed by the Virginia Board of Pharmacy, in addition to registering as a non-resident pharmacy.

111. NECC was registered in the Commonwealth of Virginia as a non-resident pharmacy, but it is not and was not registered as a wholesale distributor of prescription drugs as required by Virginia Code §54.1-3435.01(A).

112. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that NECC was not registered to distribute prescription drugs wholesale in the Commonwealth of Virginia.

113. Insight Imaging-Roanoke and its employees and agents knew that the methylprednisolone acetate that they would purchase from a pharmacy would be injected directly into patients' spinal canals so as to enter the central nervous system.

114. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the central nervous system is a relatively closed system, making treatment options more difficult in the event of an adulterated invasion.

115. Insight Imaging-Roanoke and its employees and agents knew, or should have known, that the methylprednisolone acetate that they would purchase from a pharmacy acts as an immune system suppressing agent, thus weakening the patient's natural ability to fight off pathogens that could possibly be included in the injection.

116. Despite what Insight Imaging-Roanoke and its employees and agents knew, or should have known, concerning NECC, they chose to purchase methylprednisolone acetate from NECC, which was an unaccredited, sprawling compounding pharmacy that: (a) produced its drugs in the same complex as a waste facility; (b) produced the drugs in bulk batches (making mistakes more likely); (c) did not properly sterilize the drugs; (d) did not operate with adequate quality control measures; (e) did not operate in a sterile environment; (f) did not have adequately representative samples of the drugs independently tested by an FDA-approved testing facility before releasing them for distribution; (g) did not comply with USP-NF standards; and (h) violated several provisions of Virginia statutes designed to protect Virginia citizens from substandard and adulterated prescription drugs.

117. Despite what Insight Imaging-Roanoke and its employees and agents knew, or should have known, concerning NECC, they voluntarily purchased methylprednisolone acetate from NECC in order to inject it into their patients' spinal canals, including Mr. Smith's spinal canal.

118. In addition, notwithstanding such knowledge, they voluntarily purchased methylprednisolone acetate wholesale from NECC without prescriptions.

119. On information and belief, Drs. Mathis and O'Brien would allege that this purchasing decision was made without their advice, consent, or knowledge.

120. On information and belief, Drs. Mathis and O'Brien would allege that at the times and places pertinent to this action they never knew that Insight Imaging-Roanoke and its employees and agents were purchasing the methylprednisolone acetate from NECC.

121. On information and belief, Drs. Mathis and O'Brien would allege that at the times and places pertinent to this action they never knew that the epidural steroid drug that they were injecting into patients' spinal canals, including Mr. Smith's spinal canal, came from NECC.

122. On information and belief, Drs. Mathis and O'Brien would allege that they never would have used the methylprednisolone acetate from NECC, including with Mr. Smith, if they had been informed that NECC was not an accredited compounding pharmacy.

123. On information and belief, Drs. Mathis and O'Brien would allege that they never would have used the methylprednisolone acetate from NECC, including with Mr. Smith, if they had been informed that NECC did not comply with all federal and state laws.

124. On information and belief, Drs. Mathis and O'Brien would allege that they never would have used the methylprednisolone acetate from NECC, including with Mr. Smith, if they had been informed that it was being produced in a facility located beside a garbage and waste facility.

125. On information and belief, Drs. Mathis and O'Brien would allege that they never would have used the methylprednisolone acetate from NECC, including with Mr. Smith, if they had been informed that it was being produced in a facility that did not comply with USP-NF standards.

126. On information and belief, Drs. Mathis and O'Brien would allege that the actions of Insight Imaging-Roanoke and its employees and agents deprived them from making informed

and reasonable patient care decisions on behalf of their patients, including Mr. Smith, concerning the information, and lack thereof, that they were provided concerning the epidural steroid drug.

127. In addition to Insight Imaging-Roanoke and its employees and agents apparently withholding information from Drs. Mathis and O'Brien, Insight Imaging-Roanoke and its employees and agents did not inform their patients, including Mr. Smith, that they were receiving a knock-off drug produced from a compounding pharmacy, much less a compounding pharmacy with the characteristics and problems as described in the preceding paragraphs.

128. On the contrary, Insight Imaging-Roanoke and its employees and agents provided their patients, including Mr. Smith, with invoices that falsely itemized the drug as "Depo-Medrol", the trademarked name brand drug manufactured by Pfizer.

129. The same invoices from Insight Imaging-Roanoke also falsely reference the National Drug Code, 0703-0051-01, (or an abbreviation of such code).

130. A redacted true and correct copy of this invoice is attached as **Exhibit B**.

131. Insight Imaging-Roanoke and its employees and agents also provided Mr. Smith and other patients with literature indicating that the injection that they had received was Depo-Medrol, the trademarked name brand drug produced by Pfizer.

132. A representative copy of this literature is attached as **Exhibit C**.

133. Further, Insight Imaging-Roanoke and its employees and agents falsely coded methylprednisolone acetate on Mr. Smith's medical and billing records using billing code J1040, the HCPCS code for the name brand drug produced by FDA-regulated Pfizer, as well as other FDA-regulated generic drug producers, such as Teva Parenteral Medicines, Inc., a/k/a SICOR Pharmaceuticals.

134. A compounded drug should not be billed with the J codes meant for commercially prepared, preservative free drugs.

135. Rather, the “unlisted” code, J3490, should be provided along with the name of the drug and the dosage administered.

136. Insight Imaging-Roanoke and its employees and agents falsely coded methylprednisolone acetate on Mr. Smith’s medical and billing records using the National Drug Code, 0703-0051-01, a unique product code that contains an FDA-assigned labeler code unique to the manufacturer of the drug.

137. Rather than disclosing that the methylprednisolone acetate injected into Mr. Smith was a compounded drug from NECC, Insight Imaging-Roanoke and its employees and agents falsely used the unique NDC code assigned to the FDA-regulated drug manufacturer, Teva Parenteral Medicines, Inc., for single dose, 80 mg/mL, preservative free, methylprednisolone acetate.

138. A copy of a representative label for the Teva Parenteral drug is attached for reference as **Exhibit D**.

139. However, Teva Parenteral Medicines, Inc., a leading generic drug manufacturer, had nothing to do with the epidural steroid injection that was provided to Mr. Smith.

140. Any reference in the records from Insight Imaging-Roanoke and its employees and agents to this Teva national drug code is simply false and completely misleading.

141. Similarly, Dr. O’Brien’s medical documentation states that the drug injected into Mr. Smith’s spinal canal was “Depo-Medrol”, the name brand drug produced by Pfizer.

142. On information and belief, Dr. O'Brien would allege that he referenced "Depo-Medrol" to indicate the name brand drug produced by Pfizer or a drug produced to the same high quality standards.

143. Mr. Smith never received Depo-Medrol or a drug produced to the same high quality standards from Insight Imaging-Roanoke and its employees and agents.

144. A true and correct copy of Dr. O'Brien's report is attached as **Exhibit E**.

145. This report was provided to Mr. Smith's primary care physician who was serving as Mr. Smith's agent.

146. Insight Imaging-Roanoke and its employees and agents uniformly misrepresented that the knock-off drug obtained from NECC and injected into Mr. Smith's spinal canal was, in fact, the name brand drug produced by Pfizer from an FDA-regulated laboratory and/or they misrepresented that it was the generic drug produced by the FDA-regulated laboratory, Teva Parenteral Medicines, Inc. Both representations were false.

147. A redacted true and correct copy of a representative page from Mr. Smith's medical/billing records from Insight Imaging-Roanoke is attached as **Exhibit F**.

148. At all times and places pertinent to this action, the methylprednisolone acetate that Insight Imaging-Roanoke and its employees and agents voluntarily purchased from NECC and then sold and provided to their patients, including Mr. Smith, was contaminated with fungus, mold, and/or other contaminants.

Mr. Smith's Medical Timeline

149. In the summer of 2012, Mr. Smith was experiencing significant lower back and lower extremity pain. He was examined by a neurosurgeon, Dr. Edgar Weaver Jr., M.D., who suggested surgery as a possible treatment for Mr. Smith if conservative treatments were

unsuccessful. Dr. Weaver suggested an epidural steroid injection as the conservative approach, and referred him to a clinic called Insight Imaging – Roanoke for the injection.

150. On September 12, 2012, Mr. Smith received an epidural steroid injection from Insight Imaging. Dr. O'Brien administered the injection of methylprednisolone acetate.

151. The typical method for receiving such an injection requires radiological facilities that allow the proper placement of the shot in exactly the right place with the assistance of equipment such as a fluoroscope. An anesthesiologist or an interventional radiologist usually performs such a procedure.

152. The injection never fully relieved Mr. Smith's back pain. On September 27, Dr. Edgar Weaver Jr., M.D., scheduled Mr. Smith for an October 3, 2012 surgery.

153. Just days before his scheduled surgery, Mr. Smith began experiencing chills, severe aching and an unusually strong headache. As the time for his surgery approached, Mr. Smith's condition grew worse.

154. On the morning of his scheduled surgery, October 3, 2012, he and his family knew something was very wrong. The medical team preparing for his surgery recognized that he was experiencing symptoms that had nothing to do with his underlying back problem.

155. Mr. Smith's surgery was cancelled and he was admitted to Roanoke Memorial Hospital on October 3, 2012 for treatment of fungal meningitis.

156. For the next 17 days, Mr. Smith underwent intensive therapy, at times suffering visual hallucinations and other side effects. He was finally discharged from Roanoke Memorial on October 19, 2012.

157. Mr. Smith's fungal meningitis was a direct and proximate result of receiving from the defendants tainted methylprednisolone acetate contaminated with fungus, mold and/or other contaminants, injected into his spinal cavity.

158. As a proximate result of the defendants' actions, Mr. Smith has suffered and continues to suffer serious bodily harm, mental anguish, economic loss (including but not limited to medical expenses) and other damages.

COUNT I – NEGLIGENCE *PER SE*

159. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

160. Virginia Code § 8.01-221 establishes that a person who is harmed by violation of a statute may recover for such harm.

161. Virginia law also establishes that:

. . . the violation of a statute or municipal ordinance adopted for public safety constitutes negligence because the violation is the failure to abide by a particular standard of care prescribed by a legislative body. A party relying on negligence *per se* does not need to establish common law negligence provided the proponent of the doctrine produces evidence supporting a determination that the opposing party violated a statute enacted for public safety, that the proponent belongs to the class of persons for whose benefit the statute was enacted and the harm suffered was of the type against which the statute was designed to protect, and that the statutory violation was a proximate cause of the injury. Halterman v. Radisson Hotel Corp., 259 Va. 171, 176-77, 523 S.E. 2d 823, 825 (2000); Virginia Elec. & Power Co. v. Savoy Constr. Co., 224 Va. 36, 45, 294 S.E. 2d 811, 817 (1982).

Schlimmer v. Poverty Hunt Club, 268 Va. 74, 78-79, 597 S.E.2d 43, 46 (2004) (quotations omitted).

162. Virginia Code §§ 54.1-3400 *et seq.* (collectively known as "The Drug Control Act") are statutes enacted for public safety, in that they protect the public from the release of

substandard and otherwise unreasonably dangerous pharmaceutical drugs and drugs into the stream of Virginia commerce.

163. As a consumer of a drug regulated by the Virginia Drug Control Act, Mr. Smith belongs to the class of persons for whose benefit those statutes were enacted.

164. A drug is deemed adulterated under Virginia law if it has been produced, prepared, packed, or held under insanitary conditions whereby it has been rendered injurious to health. Va. Code § 54.1-3461(A)(2).

165. Additionally, a drug is considered adulterated if it purports to be a drug recognized in an official compendium, but fails to meet the quality or purity standards set forth in the compendium or the federal act. Va. Code § 54.1-3461(B).

166. By holding and offering for sale an adulterated drug to its patients, including Mr. Smith, Insight Imaging-Roanoke and its employees and agents violated Virginia Code § 54.1-3457(1), which is part of the Virginia Drug Control Act.

167. By receiving an adulterated drug in commerce and then delivering the drug for pay to its patients, including Mr. Smith, Insight Imaging-Roanoke and its employees and agents violated Virginia Code § 54.1-3457(3), which is part of the Virginia Drug Control Act.

168. Mr. Smith's fungal meningitis was the result of the actions of Insight Imaging-Roanoke and its employees and agents in receiving, holding, selling, and providing to him an adulterated drug.

169. The adulterated drug injected into Mr. Smith's spinal canal contained fungal pathogens that proximately caused him to develop fungal meningitis.

170. Death or injury of a patient resulting from consumption of or contact with adulterated drugs belongs to the category of harms against which the Virginia Drug Control Act was designed to protect.

171. Death or injury of a patient resulting from consumption of or contact with adulterated drugs distributed wholesale by an entity engaging in the wholesale distribution of prescription drugs in the Commonwealth of Virginia without a valid license belongs to the category of harms against which Virginia Drug Control Act was designed to protect.

172. Therefore, each of the violations of the above statutes (Virginia Code § 54.1-3457(1), and Virginia Code § 54.1-3457(3)) by Insight Imaging-Roanoke and its employees and agents constitutes negligence *per se*, and Mr. Smith is entitled to the recovery of damages for his unnecessary fungal infection and personal injury.

COUNT II – VIRGINIA CONSUMER PROTECTION ACT

173. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

174. Mr. Smith engaged in a consumer transaction with Insight Imaging-Roanoke and its employees and agents as defined in Virginia Code § 59.1-198.

175. Insight Imaging-Roanoke and its employees and agents were suppliers of the tainted methylprednisolone acetate injected into Mr. Smith's spinal canal.

176. Insight Imaging-Roanoke and its employees and agents violated Virginia Code § 59.1-200, which prohibits suppliers from misrepresenting goods as those of another, misrepresenting the source, sponsorship, approval or certification of goods, and misrepresenting that goods are of a particular standard, quality, grade or model.

177. These willful violations by Insight Imaging-Roanoke and its employees and agents resulted in Mr. Smith's fungal meningitis.

178. Mr. Smith is entitled to the recovery of damages for his unnecessary fungal meningitis and personal injury.

179. All of these actual damages occurred as the result of the violations of Virginia Code § 59.1-200 by Insight Imaging-Roanoke and its employees and agents.

180. Further, Mr. Smith is entitled to treble damages and an award of attorneys' fees, costs, and expenses incurred in this matter.

COUNT III – NEGLIGENCE

181. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

182. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to ensure that the drugs that they purchased in order to sell and inject in their patients, including Mr. Smith, came from drug companies that complied with Virginia laws regarding pharmaceutical drugs ("The Virginia Drug Control Act" statutes).

183. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to ensure that their purchase of the drug they provided to Mr. Smith complied with the Virginia Drug Control Act.

184. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to ensure that the drugs they purchased in order to sell and administer to their patients, including Mr. Smith, were purchased from drug manufacturers that utilized proper quality control, safety, and sterility measures in order to minimize the possibility that the drugs would become adulterated.

185. Insight Imaging-Roanoke and its employees and agents had a duty to inform the doctors practicing at it, including Drs. Mathis and O'Brien, about the purchasing decisions by Insight Imaging-Roanoke to obtain drugs from NECC and about NECC. To the extent that they did not do so, they violated their duty and their violation prevented the doctors practicing at it, including Drs. Mathis and O'Brien, from making knowledgeable and professionally reasonable decisions to reject such drug on behalf of Mr. Smith and their other patients.

186. Insight Imaging-Roanoke and its employees and agents had a duty to provide adequate medical oversight regarding the purchase of drugs such as the one at issue in this case. To the extent that Insight Imaging-Roanoke had no official medical director during the time and places pertinent to this action, then they delegated to non-medical staff the important patient care function of choosing safe drugs for their patients.

187. Insight Imaging-Roanoke and its employees and agents had a duty to exercise reasonable care to avoid injecting Mr. Smith with adulterated drugs.

188. Insight Imaging-Roanoke and its employees and agents had a duty to know what they were injecting into patients, including Mr. Smith.

189. Insight Imaging-Roanoke and their employees and agents had a duty to provide Mr. Smith reasonable care and treatment when he came to them for treatment.

190. Insight Imaging-Roanoke and its employees and agents had a duty to obtain informed consent from Mr. Smith for the procedure performed on him, adequately and accurately describing to him the nature of the procedure, as well as the risks of such procedure.

191. In this case, where the methylprednisolone acetate came from an unaccredited, mass producing, out-of-state, compounding pharmacy, (unregulated by the FDA and surrounded

by a garbage and waste facility), Insight Imaging-Roanoke and its employees and agents had a duty to inform Mr. Smith of the source of the drug and the dangers associated therewith.

192. Insight Imaging-Roanoke and its employees and agents breached their duties to Mr. Smith in many respects:

- a. They failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Mr. Smith was made in compliance with Virginia pharmaceutical laws;
- b. They failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Mr. Smith was sold to them in compliance with Virginia pharmaceutical laws;
- c. They failed to know and understand the source and supply of the drug they provided to Mr. Smith;
- d. They failed to exercise reasonable and prudent care to ensure that the drug they provided to Mr. Smith was produced in sanitary, sterile conditions;
- e. They failed to properly inform Mr. Smith that the epidural steroid injection was an "off-label" application of the drug at issue, not approved by the FDA for such an application;
- f. They failed to properly inform Mr. Smith of the risks and dangers associated with the injection of the drug; and they failed to inform him that they had obtained the drug from NECC, the mass-producing, unaccredited, non-FDA regulated compounding pharmacy surrounded by a garbage recycling facility;
- g. Alternatively to the preceding allegation, to the extent that Insight Health unilaterally made the decision to purchase the tainted steroid and kept important information regarding the actual source and identity of the methylprednisolone acetate from Drs. Mathis and O'Brien, it failed to exercise reasonable and prudent care to ensure that Mr. Smith's physician was adequately informed so as to allow his doctor to make knowledgeable and professionally reasonable decisions to reject such drug on behalf of Mr. Smith and other similarly situated patients;
- h. They failed to exercise reasonable care to avoid injecting Mr. Smith with an adulterated drug;
- i. To the extent that Insight Imaging – Roanoke had no official medical director (who would have reviewed the source and supply of drugs) during the time periods relevant to this proceeding, then all or some of the defendants delegated to non-medical staff the important patient care function of choosing safe drugs for

patients; and they deviated from the standard of care and breached their duties in so doing;

- j. They failed to act ethically;
- k. They failed to act with integrity;
- l. They failed to put patient care first;
- m. They failed to do the right thing;
- n. They put profits over ethics;
- o. They put profits over integrity;
- p. They put profits over patient care; and
- q. In such other manners as may be shown through discovery and at trial.

193. The negligence of Insight Imaging-Roanoke and its employees and agents proximately caused Mr. Smith's fungal meningitis.

194. Mrs. Smith is entitled to the recovery of damages for his unnecessary fungal meningitis and personal injury.

COUNT IV – GROSS NEGLIGENCE

195. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

196. The foregoing acts and omissions by Insight Imaging-Roanoke and its employees and agents went beyond mere thoughtlessness, inadvertence or error of judgment.

197. Rather, the actions of Insight Imaging-Roanoke and its employees and agents did not meet even the most minimal diligence to ensure that they were not injecting adulterated and tainted drugs directly into the bodies of their patients, including Mr. Smith.

198. The acts and omissions of Insight Imaging-Roanoke and its employees and agents constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Mr. Smith.

199. The acts and omissions of Insight Imaging-Roanoke and its employees and agents were a heedless and palpable violation of their legal duties respecting the life and rights of Mr. Smith. Frazier v. City of Norfolk, 234 Va. 388, 393, 362 S.E.2d 688, 691 (1987).

200. Mr. Smith's fungal meningitis occurred as a proximate result of the grossly negligent acts and omissions of Insight Imaging-Roanoke and its employees and agents.

COUNT V – FRAUD

201. The preceding paragraphs are hereby incorporated as if they were fully set forth herein.

202. Insight Imaging-Roanoke and its employees and agents did not inform their patients, including Mr. Smith, that they were providing drugs produced from a compounding pharmacy, much less a compounding pharmacy with the characteristics and problems described in the preceding paragraphs.

203. Insight Imaging-Roanoke and their employees and agents had a duty to inform their patients of these facts which were possessed solely by them and which they knew were unknown to Mr. Smith and other patients.

204. The decision by Insight Imaging-Roanoke and its employees and agents not do so constituted actual and/or constructive fraud.

205. Insight Imaging-Roanoke and its employees and agents had a duty to adequately inform the doctors practicing at it, including Drs. Mathis and O'Brien, about the purchasing decisions by Insight Imaging-Roanoke to obtain drugs from NECC and about NECC. To the

extent that they did not do so, they violated their duty and their violation prevented the doctors practicing at it, including Drs. Mathis and O'Brien, from making knowledgeable and professionally decisions to reject such drugs on behalf of Mr. Smith and their other patients.

206. Insight Imaging-Roanoke and its employees and agents provided patients, such as Mr. Smith, with written false documentation asserting that the drug injected was, in fact, the name brand drug produced by the FDA-regulated manufacturer, Pfizer.

207. Also, Insight Imaging-Roanoke and its employees and agents provided patients, such as Mr. Smith, with written false drug code documentation asserting that the drug injected into the patient was, in fact, the generic version of the drug produced by the FDA-regulated manufacturer, Teva Parenteral Medicines, Inc., National Drug Code, 0703-0051-01 (single dose, 80 mg/mL, preservative free, methylprednisolone acetate).

208. Within the context of the healthcare provider-patient relationship, Mr. Smith relied upon the superior knowledge of Insight Imaging-Roanoke and its employees and agents concerning the drug, source of the drug, and cost of the drug in accepting their representation that the methylprednisolone acetate was safe and effective.

209. Insight Imaging-Roanoke and its employees and agents provided Mr. Smith with a knock-off drug obtained from an unaccredited compounding pharmacy, unregistered to distribute wholesale in Virginia, and not preferred by insurance companies – including Mr. Smith's insurance company, without disclosing information about its source.

210. In so doing, Insight Imaging-Roanoke and its employees and agents concealed facts material to Mr. Smith's treatment, knowing Mr. Smith acted on the belief that no such facts existed, and that Mr. Smith relied upon it to obtain and inject safe drugs.

211. By representing that the drug injected was obtained from an FDA-regulated manufacturer, Insight Imaging-Roanoke and its employees and agents misrepresented a material fact regarding Mr. Smith's treatment.

212. Rather than properly informing its patients, including Mr. Smith, of these crucial facts, Insight Imaging-Roanoke and its employees and agents falsely represented the drug at issue as "Depo-Medrol," the trademarked name brand used by Pfizer; and falsely coded it as the generic version of the drug produced by the FDA-regulated manufacturer, Teva Parenteral Medicines, Inc., National Drug Code, 0703-0051-01 (single dose, 80 mg/mL, preservative free, methylprednisolone acetate).

213. This pattern of deception by Insight Imaging-Roanoke and its employees and agents was repeated to Mr. Smith's primary care physician.

214. This pattern of deception by Insight Imaging-Roanoke and its employees and agents was also repeated for billing purposes to Mr. Smith's insurance company, where Insight Imaging-Roanoke falsely used the National Drug Code, 0703-0051-01, a unique product code assigned to the completely unrelated FDA-regulated drug manufacturer, Teva Parenteral Medicines, Inc.

215. Insight Imaging-Roanoke also used an HCPCS "J" code inappropriate and misleading for compounded drugs.

216. Such actions by Insight Imaging-Roanoke and its employees and agents show affirmative misrepresentations of the identity of the drug provided to Mr. Smith and a knowing, deliberate decision not to disclose the source of the "drug" provided to Mr. Smith.

217. As a third party payor and agent authorized to receive medical invoices for processing on behalf of Mr. Smith, misrepresentations to Mr. Smith's health insurer constitute misrepresentations to him.

218. Mr. Smith's health insurer, like many such third-party payors, maintains policies discouraging the use of compounded drugs.

219. For example, Anthem Blue Cross states as follows:

Compounded medications are customized medication(s) ... that are not commercially available ... However, they are not approved by the U.S. Food and Drug Administration (FDA) nor are they approved by our Pharmacy and Therapeutics process. **Since there is limited oversight in the preparation of these compounded medications, there is a possibility that patients may be put at risk when prescribed a compounded medication that is not subject to quality testing that validates purity, stability or dosage...** Thus, due to the lack of data to adequately review these medications, compounded medications are considered **non-preferred**... They may also require prior authorization of benefits for coverage through a participating network pharmacy...

220. On information and belief, Insight Imaging-Roanoke and its employees and agents knew that using drugs from compounding pharmacies would present billing issues and problems with reimbursement.

221. On information and belief, Insight Imaging-Roanoke and its employees and agents knew that properly coding the drugs injected into Mr. Smith and other patients would cause concerns and "red flags" with insurance companies, such as the one serving Mr. Smith.

222. Accordingly, on information and belief, Insight Imaging-Roanoke and its employees and agents specifically chose to falsely describe the drugs provided as part of a scheme and common practice or design, intended to prevent insurance companies from realizing the nature and source of the drugs being injected into patients, such as Mr. Smith.

223. Insurance companies, such as the one serving Mr. Smith, act as a protective information source and gatekeeper for their customers.

224. Here, Insight Imaging-Roanoke and its employees and agents engaged in the same pattern of behavior (and the same specific misrepresentations to patients, referring primary care physicians, and insurers provided by the defendants to Mr. Smith, his doctor and his insurer) with many other patients receiving epidural steroid injections.

225. These specific actions relating to Mr. Smith and the prolonged pattern of deception prevented Mr. Smith's insurer from properly performing its protective role. As a result, Insight Imaging-Roanoke was able to continue its practice of purchasing methylprednisolone acetate from NECC and passing it off as a manufactured and safe drug.

226. Under these circumstances, misrepresentations to Mr. Smith's insurer – particularly as part of a pattern of conduct – constituted misrepresentations to Mr. Smith that were material and relied upon to his detriment.

227. Insight Imaging-Roanoke and its employees and agents misrepresented that the knock-off drug obtained from NECC and injected into Mr. Smith's spinal canal was, in fact, the name brand drug produced by Pfizer from an FDA-regulated laboratory; they misrepresented the code for such drug as the generic drug produced by the FDA-regulated laboratory, Teva Parenteral Medicines, Inc.

228. These representations (and the pattern of which they were a part) were false and deceptive, were relied upon to the detriment of Mr. Smith (and/or his agent insurer) and other patients, and caused harm to Mr. Smith.

229. Insight Imaging-Roanoke and its employees and agents knew, or should have known, these representations to be false.

230. These representations and the pattern of similar behavior by Insight Imaging-Roanoke and its employees and agents constitute actual or constructive fraud.

CERTIFICATION PURSUANT TO VIRGINIA CODE § 8.01-20.1

231. Mr. Smith certifies that he complied with Virginia Code § 8.01-20.1 before requesting service of process upon the defendants.

REQUEST FOR TRIAL BY JURY

232. Mr. Smith requests trial by jury on all issues.

PRAYER FOR RELIEF

WHEREFORE, James Wirt Smith, Jr., by counsel, moves this Court for judgment against the defendants, jointly and severally, in the amount of FIVE MILLION DOLLARS (\$5,000,000) plus his taxable costs with pre-verdict interest from September 12, 2012 and post-verdict interest on all of these amounts, as well as \$350,000 in punitive damages, trebled damages, attorney's fees, and costs.

JAMES WIRT SMITH, JR.,


By Counsel

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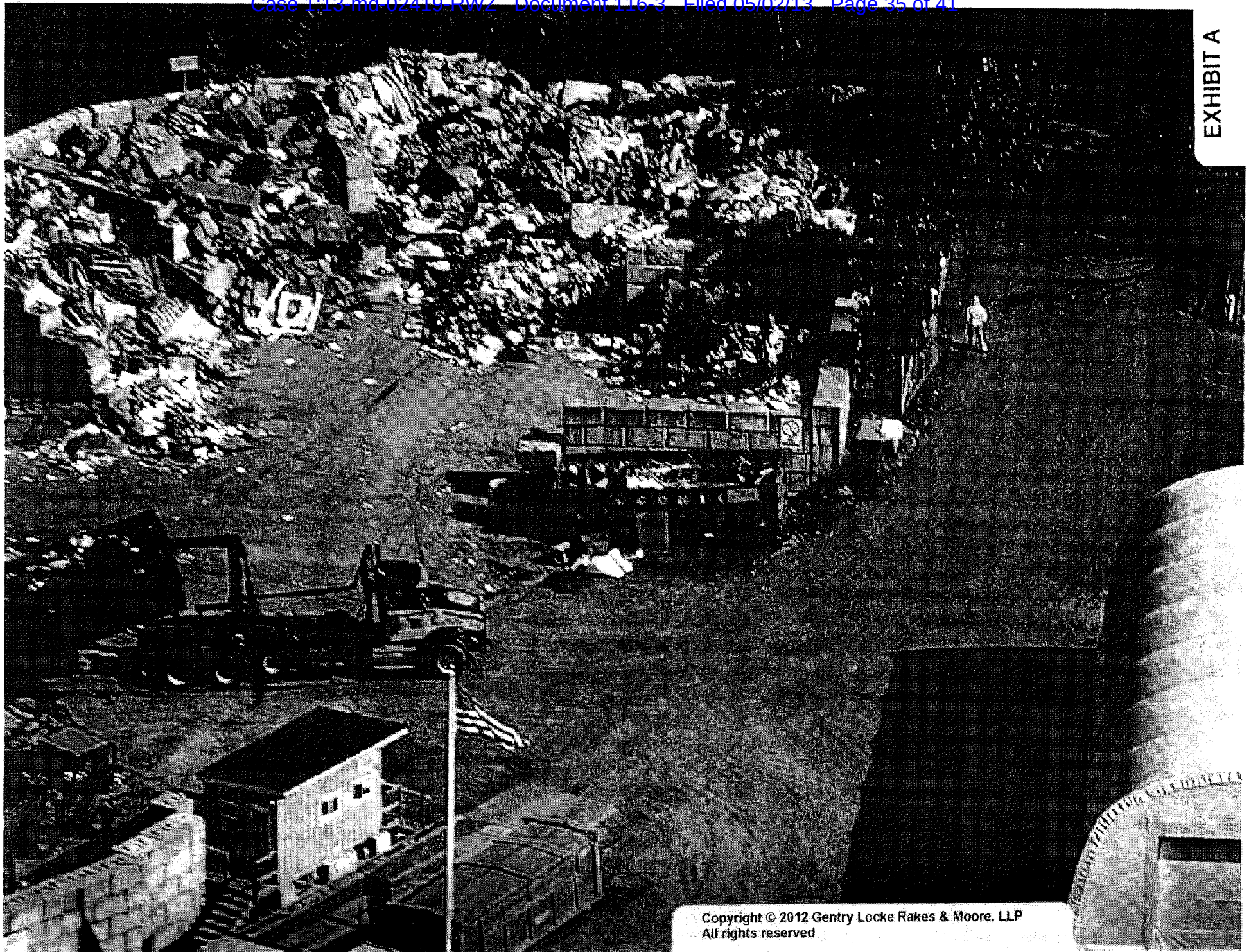


EXHIBIT A

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MAKE CHECKS PAYABLE TO:

Insight Imaging Roanoke
PO Box 843086

Los Angeles, CA 900843086

STATEMENT DATE	PAY THIS AMOUNT	ACCOUNT NBR
11/09/12	CONTINUED	
SHOW AMOUNT PAID HERE \$		

STATEMENT

ADDRESSEE:

SMITH, JAMES

REMIT TO:

Insight Imaging Roanoke
PO Box 843086
Los Angeles, CA 900843086

☐ Please check box if above address is incorrect or insurance information has changed, and indicate change(s) on reverse side.

PLEASE DETACH AND RETURN TOP PORTION WITH YOUR PAYMENT

DATE	DESCRIPTION OF SERVICE	AMOUNT	INSUR BALANCE	PATIENT BALANCE	BALANCE	
09/12/12	ENCOUNTER FOR JAMES WITH OBRIEN MD, ROBERT					
09/12/12	62311-G - INJ 1 NOT LYTIC-W/WO CM-DX/TX-EPIDUR; LUMB/SAC					
09/14/12	PAYMENT					
09/25/12	PAYMENT					
10/26/12	PAYMENT					
09/12/12	77003-G - FLUOROSCOPIC GUIDANCE AND LOCALIZATION OF NE...					
09/14/12	PAYMENT					
09/25/12	PAYMENT					
10/26/12	PAYMENT					
09/12/12	00270141125C - ISOVUE M 200 BRACCO (QTY 2)					
09/14/12	PAYMENT					
09/25/12	PAYMENT					
10/26/12	PAYMENT					
09/12/12	00703005101M - DEPO-MEDROL METHYLPREDNISOLONE					
09/14/12	PAYMENT					
09/25/12	PAYMENT					
10/26/12	PAYMENT					
09/12/12	0040948820M - SODIUM CHLORIDE INJECTION					
09/14/12	PAYMENT					
09/25/12	PAYMENT					
10/26/12	PAYMENT					
09/12/12	00409155910M - MARCAINE BUPIVACAINE					
09/14/12	PAYMENT					
09/25/12	PAYMENT					
10/26/12	PAYMENT					
09/12/12	\$A4649S - SURGICAL SUPPLY; MISCELLANEOUS					
09/14/12	PAYMENT					
09/25/12	PAYMENT					
10/26/12	PAYMENT					
09/12/12	ENCOUNTER TOTAL					
ACCOUNT NBR	CURRENT	30 DAYS	60 DAYS	90 DAYS	120 DAYS	TOTAL ACCOUNT BALANCE
		\$0.00	\$0.00	\$0.00	\$0.00	

MESSAGE:

PLEASE PAY
THIS AMOUNT »»»» CONTINUED

** PAYMENT DUE UPON RECEIPT * THANK YOU **
STATEMENT

PAGE: 1

EXHIBIT B

John M. Mathis, M.D., M.Sc.

INSIGHT
IMAGING

INSIGHT IMAGING ROANOKE
2923 FRANKLIN ROAD S.W.
ROANOKE VA 24014

Tel: 540.581.0882
Fax: 540.581.0881

www.insighthealth.com

Date: _____

Injection dosage: Depo-Medrol 80mg / 40mg

Steroids typically take 12 to 24 hours before they start to work.
Maximum effect can take up to 7 – 10 days.

Call **Insight Imaging (540-581-0882)** in a week if symptoms have not subsided to schedule another injection. If you already have an appointment scheduled with Insight, keep that appointment unless otherwise directed by your physician.

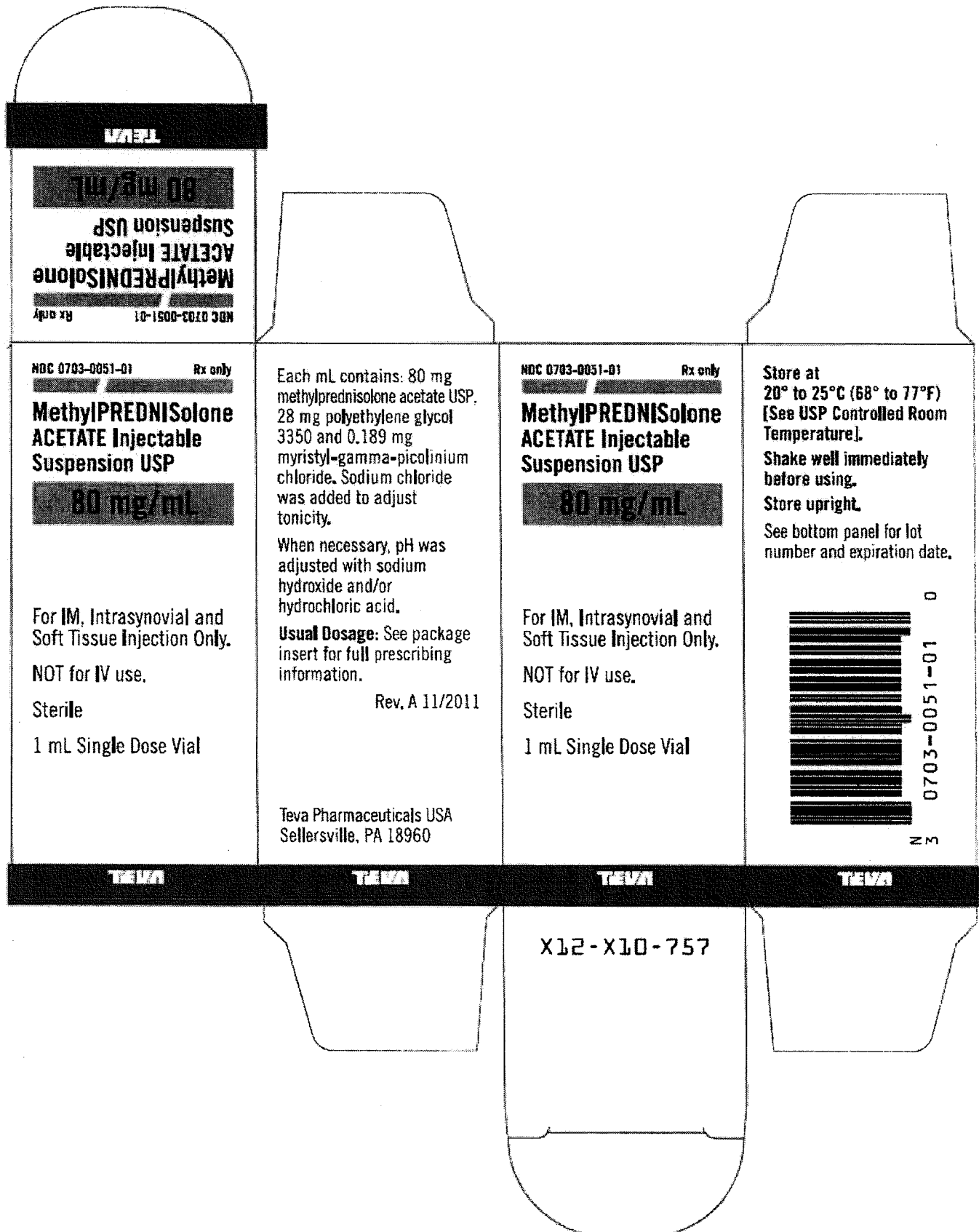
If your pain has completely resolved, and you no longer need your follow up appointment, please call Insight Imaging to cancel your future injection.

Continue to take pain meds if needed.
Heat or ice may be used as well.

Symptoms can worsen before seeing improvement.

****Call your Doctor that monitors your Diabetes or Blood Pressure if you feel you are higher than the guidelines set by your physician.

PRINCIPAL DISPLAY PANEL





Insight Imaging – Roanoke
2923 Franklin Road
Roanoke, VA 22206
PH# 540.581.0882
FAX# 540.581.0881

PATIENT NAME: SMITH, JAMES
PATIENT DOB:
DATE OF EXAM: 09/12/2012
REQUESTED BY: EDGAR WEAVER JR, MD

EXAM: INJ 1 NOT LYTIC-W/WO CM-DX/TX-EPIDUR; LUMB/SAC

CLINICAL HISTORY: Lumbar radiculopathy.

INJECTION SITE: The study is performed near the midline at L3-4.

TECHNIQUE: After informed consent was obtained, the patient was brought to the fluoroscopy suite. Preliminary fluoroscopy was performed. Entry site and angulation were determined.

Following sterile preparation and drape and with the use of lidocaine as a local anesthetic, a 25-gauge spinal needle was advanced to the posterior epidural space. Small puffs of contrast were administered. Once needle tip location was confirmed in the posterior epidural space, a mixture of Depo-Medrol and dilute Marcaine was administered. A total of 80 mg of Depo-Medrol was given. The patient tolerated the procedure well and left the department in stable condition.

IMPRESSION:
SUCCESSFUL LUMBAR EPIDURAL STEROID INJECTION.

Thank you for this referral.

Robert F. O'Brien, M.D.
RFO/lk

D: 09/12/2012 10:48:48PDT

T: 09/12/2012 11:04:32PDT

Doc ID: 12124210/Insight Job ID: 2356344/NTS Job ID: 2356344/10258062
10258062

Document authenticated by Robert F. O'Brien, M.D., on 09/12/2012 11:29:13PDT

Procedure Completion						
				Send HL7 Hx (0)		Exam 1 of 1
Patient Name: SMITH, JAMES DOB: [redacted] Phone: [redacted] Sex: M Age: 64 SSN: [redacted]			Visit Service Date: 8/12/2012 Appt Type: S		Is Patient Pregnant: Yes No Date of LMP: MM/DD/YYYY	
Accession	CPT Code	CPT Description	Modality	Start Time	End Time	
10258062	62311	EPIDURAL(ESI) LUMBAR	3PC	3:00 PM	3:30 PM	
Performed Procedure - 10258062 Prim Diag: [redacted] PD CPT Cd/Desc: 62311 EPIDURAL(ESI) LUMBAR Qty: 1 Start/End: 1:35 PM 1:45 PM Contrast Seq w/ [redacted] Seq w/o [redacted] Total: 1.00 <input checked="" type="checkbox"/> HCPCS_A4649 - SURGICAL SUPPLY; MISCELLANEOUS <input checked="" type="checkbox"/> 77003 - FLUOROSCOPIC GUIDANCE AND LOCALIZATION C Radiologist: OBRIEN, ROBERT Radiation Dose: No Dose Available DLP: mGy-cm Misc. Info: Cancellation: [redacted]						
Contrast/Isotope/Sedation/Supplies						
Bill Qty	HCPCS Cd	HCPCS Description	NDC	Accession		
2	Q9966	LOW OSMOLAR CONTRAST MATERIAL, 200-299 MG/ML IODINE	00270141125	10258062		
1	J1040	INJECTION, METHYLPREDNISOLONE ACETATE, 80 MG	00703005101	10258062		
1	A4216	STERILE WATER, SALINE AND/OR DEXTROSE, DILUENT/FLUSH,	00409488820	10258062		
1	J3490	UNCLASSIFIED DRUGS	00409155910	10258062		
Sedation/Meds Brand: DEPD MEDROL METHYLPREDNISOLONE Strength: 80 MG/ML Route: EPIDURAL Delivery: 1 ML NDC #: 00703005101 Amt Admin: [redacted] ML Sedation Note: [redacted] Lot #: 06292012 Exp. Dt: 12/26/2012 Admin By: RFO (Initials) [Ok] [Cancel]						
Contrast Edit Sed/Med Delete Isotope Supply						

EXHIBIT F